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09/574,461	05/18/2000	Roger J. Talish	601-61	6818

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EXAMINER

QADERI, RUNA S

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 11/04/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/574,461

Applicant(s)

TALISH ET AL.

Examiner

Runa S. Qaderi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Specification***

The disclosure is objected to because of the following informalities: The specification is inconsistent in the teaching to the direction of the magnetic flux with respect to the acoustic wave for providing the maximum effect or perturbation of the acoustic wave. Examiner directs attention to page 18 of specification, specifically to the description of figures 5B and 7B. Applicant discloses that the arrangement of the coil with respect to the transducer influences to what extent the acoustic wave is perturbed by the electromagnetic wave. Applicant teaches that the arrangement of figure 5B produces the smallest perturbation and that of figure 7B produces the greatest perturbation to the acoustic wave. Specification page 20, specifically description to figure 9, is inconsistent with the teaching of specification page 18. Applicant recites that the first coil 48 (same coil and transducer arrangement as that of figure 7B) slightly modulates the acoustic wave while the second coil 50 (same coil and transducer arrangement as that of figure 5B) greatly modulates the acoustic wave.

Appropriate correction is required.

### ***Claim Objections***

Claims 24-29 are objected to because of the following informalities: The preamble of the base claim 24 pertains to the application of ultrasonic waves whereas the body of the claim pertains to "pressure waves". The two recitations are inconsistent. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 8, 9, 10-13, 18, 19, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Edrich et al. (US 5,476,438).

Edrich et al. teaches a method and apparatus of neuromagnetic simulation. The patent simultaneously directs focused beam of ultrasonic waves with an applied magnetic field to simulate a region of interest. Fig 3 of Edrich et al. depict a schematic of the system including ultrasound transducer source (1) which focuses the ultrasound waves into a region, coils (7) that produce magnetic fields, drivers 16 and 17 for providing a driving signal to the transducer and coil, respectively. A synchronizer (18) and delay circuit (19) perform the function of frequency and phase control of the magnetic and ultrasound signals. The synchronizer (18) and delay circuit (19), and drivers (16 and 17) function as the main operating unit for driving the ultrasound transducer and magnetic coils. The patent teaches that the system can enclose the head in a helmet-like fashion thereby satisfying the applicant's limitation to a placement module configured to be worn by the patient, column 5 lines 1-5. The coupling of driver 16 and 17 to ultrasound source and magnetic coils, respectively, as shown in figure 3 teaches the limitation to a first and second cable. The teachings to frequency and phase control of the ultrasound and magnetic waveforms encompasses the step of

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varying the magnitude of the waveform as taught by applicant, column 3 line 51 through column 4 line 6. Furthermore the patent teaches that the relationship of the applied ultrasound and magnetic waves is adjusted to achieve optimum stimulation performance. To reiterate Edrich et al. teaches the direction of the acoustic waves with respect to the magnetic wave enhanced the therapeutic procedure, in that a magnetic field with a magnetic induction (flux)  $B$  orthogonal to the focused ultrasound wave will result in enhanced or improved therapy to the region of interest, column 2. The magnetic field and the ultrasound wave are applied simultaneously, furthermore a superimposition of the two waves occurs. This superimposition of the acoustic and magnetic wave is interpreted as the modulation of the applicant claims.

Superimposition is defined as to lay on top, given this definition it satisfied the limitation to modulate the signals. Finally the limitations to a conductive material that couples main operating unit to the at least one ultrasound transducer and at least one coil and the non-uniform magnetic field are inherent to the functionality of the invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 3-5, 14, 15, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich et al. (US 5,476,438).

Edrich et al. teaches simultaneous application of ultrasound and magnetic waveforms to stimulate a region of interest. The patent teaches that the relationship of the two waveforms affects the extent of therapy that is received by the tissue. Furthermore it is taught that applying the magnetic flux orthogonal to the ultrasound waveform optimizes the therapeutic procedure. Figure 3 of Edrich et al. patent is a schematic of the system, the coils 7 appear to be orthogonal to the ultrasound transducer.

The patent does not describe in angular positioning of transducer and coil with respect to each other. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide angular descriptions because figure 3 satisfies a angle  $\theta$  greater than or equal to zero and less than or equal to 90 degrees.

The patent does not explicitly recite the coil wrapped around the placement module or the transducer placed closer to treatment area than coil. It would have been obvious to a person of ordinary skill in the art to have alternatively provided these configurations so as long as the magnetic flux is orthogonal to ultrasound wave thereby enhancing or optimizing therapy as taught by Edrich et al.

Claims 7, 16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich et al. (US 5,476,438) in view of Slayton et al. (6,050,943).

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The system and method of Edrich et al. teaches simultaneous magnetic and ultrasound application for region stimulation. Edrich et al. does not teach a further diagnostic capability of the ultrasound transducer. Slayton et al. teaches a single ultrasound transducer that can both image and treat tissue. It would have been obvious to a person of ordinary skill in the art to have further incorporated an imaging capability, thereby receiving diagnostic ultrasound signals, to the transducer of Edrich et al. because simultaneous real-time monitoring of the therapeutic procedure using a single component is a well-known expedient in the art. In addition a more efficient therapeutic procedure is enabled as taught by Slayton et al.

Claims 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich et al. (US 5,476,438) in view of Talish et al. (5,556,372).

Edrich et al. teaches a method and apparatus of neuromagnetic simulation. The patent simultaneously directs focused beam of ultrasonic waves with an applied magnetic field to simulate a region of interest. Fig 3 of Edrich et al. depict a schematic of the system including ultrasound transducer source (1) which focuses the ultrasound waves into a region, coils (7) that produce magnetic fields, drivers 16 and 17 for providing a driving signal to the transducer and coil, respectively. A synchronizer (18) and delay circuit (19) perform the function of control means to vary the applied ultrasound and magnetic waves, column 3-4. The patent teaches that the system can enclose the head in a helmet-like fashion, column 5 lines 1-5. The teachings to adjusting the two waveforms encompass variation of the spatial distribution of the

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waves. Furthermore the patent teaches that the relationship of the applied ultrasound and magnetic waves is adjusted to achieve optimum stimulation performance. To reiterate Edrich et al. teaches the direction of the acoustic waves with respect to the magnetic wave enhanced the therapeutic procedure, in that a magnetic field with a magnetic induction (flux)  $B$  orthogonal to the focused ultrasound wave will result in enhanced or improved therapy to the region of interest, column 2. The magnetic field and the ultrasound wave are applied simultaneously, furthermore a superimposition of the two waves occurs. This superimposition of the acoustic and magnetic wave is interpreted as the modulation of the applicant claims. Superimposition is defined as to lay on top, given this definition it satisfied the limitation to modulate the signals.

The patent does not teach the specific structural components of the therapeutic apparatus. Talish et al. teaches an ultrasound therapeutic apparatus, figures 1 and 3. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have alternatively provided the coil and transducer means as the portable configuration of Talish et al. figure 3 because it allows for patient mobility while optimizing therapy. Further it can be positioned to administer therapy to any desired region rather than the helmet like structure of Edrich et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 8:00-4:30.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis W. Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*RSQ*

RSQ

*Eleni Mantis Mercader*  
ELENI MANTIS MERCADER  
PRIMARY EXAMINER  
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